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EXAMINER
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ART UNIT	PAPER NUMBER
2644	3

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/082,989	Applicant(s) MILLER ET AL.	
	Examiner Tony M. Jacobson	Art Unit 2644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 16-33* is/are rejected.

7)☒ Claim(s) *14 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 20 recites the limitation "the reference signal" in line 9 (of the claim). There is insufficient antecedent basis for this limitation in the claim. There is no prior mention of a reference signal in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-12 and 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer (USPN 6,554,762) in view of Durand (USPN 6,154,023).

7. Regarding claims 1 and 20, Leysieffer discloses in Fig. 1, an implantable hearing aid with means for measuring its coupling quality, which comprises a signal generator (DSP 13 in combination with microcontroller 17) to output a test signal at a predetermined frequency, that generates an electrical signal passing through an implanted hearing aid actuator (16); a measurement device (25) to generate at least one test measure (the impedance) of the electrical signal; and a signal processing unit (13) to process the impedance measure to assess at least one performance parameter of the hearing aid. Leysieffer does not disclose a measurement device to measure a magnetic field generated by the implanted hearing aid actuator; rather, the system of Leysieffer determines the current through the actuator more directly by measuring a voltage drop across a current sampling resistor ("Rm" in Fig. 2). In Fig. 11, Leysieffer discloses an embodiment of the invention in which the hearing aid is a partially-implanted type, including the elements of Fig. 1 (sans telemetry system 20), in which a passive electronics module (74) is implanted along with a transducer (16 or 36), and in

which the remainder of the electronics are disposed in an external unit (76). The specific details of this embodiment are described at column 20, line 64 through column 21, line 13, where Leysieffer discloses that the impedance measuring system (25) of Fig. 1 is included in the implanted portion of the hearing aid. Durand discloses in Fig. 1, a system for remotely measuring a current in an implanted medical device using a pair of sensors to measure a generated magnetic field. Since one of ordinary skill in the art would recognize that the voltage applied to the actuator (16 or 36) could be estimated in the external unit (76) based on the level at which a signal is transmitted to the implanted passive electronics module (77) by the external unit, it would have been obvious to one of ordinary skill in the art at the time the present invention was made to substitute the remote current sensing system of Durand, located in the external unit (76), for the implanted impedance measuring system of Leysieffer to create a test system that does not require the passive electronics module (77) to transmit measurement data back to external unit (76), thus simplifying the structure of implanted passive electronics module (77) and reducing its power requirements. The inherent normal method of testing the quality of coupling of the actuator to a component of a patient's auditory system according to the system of Fig. 11 of Leysieffer, modified by the teachings of Durand as described above would comprise positioning a test measurement device (76) external to a patient having the implanted actuator (16 or 36); utilizing the test measurement device to obtain at least one measure of a magnetic field generated the actuator in response to an electrical signal passing through the actuator

(claim 13); and employing the at least one magnetic field measure to assess the performance of the actuator (claim 1).

8. Regarding claims 2, 3, 21, and 22, Leysieffer discloses at column 6, lines 46-63 that means are provided for objectively determining the quality of coupling between the output transducer (actuator) and the coupled auditory element based on the measured impedance. Objective determination based on measured quantities inherently comprises comparing the measured quantities to one or more predetermined ranges. Leysieffer discloses at column 13, line 66 through column 14, line 7 that the microcontroller (17) of the implanted hearing aid communicates bi-directionally through the closed skin with an external programming system (22), which can advantageously be a PC-based system with the corresponding programming, processing, display, and administration software. Although Leysieffer does not explicitly disclose the detailed nature of the output provided to the operator of the system, one of ordinary skill in the art would conclude that means are included within the programming system to provide a user-interface output, via a display of the PC-based programming system, indicative of whether the measured quantities are within predetermined ranges.

9. Regarding claims 4 and 23, it would have been obvious to one of ordinary skill in the art at the time the present invention was made to compare the measured impedance value obtained by the system of Leysieffer with any desired number of predetermined ranges which are at least partially non-overlapping, utilizing appropriate means, in order to categorize the test results. Further, it would have been obvious to make a plurality of ranges at least partially non-overlapping, since if the ranges were not

at least partially non-overlapping, they would be identical and the results of the comparisons would duplicate each other.

10. Regarding claims 5 and 24, one of ordinary skill in the art would conclude that means are included and utilized in the system of Leysieffer to provide an output indicative of whether the measured quantities are within the predetermined ranges, otherwise the results of the measurements would be useless and the device would be non-functional with respect to the desired test function.

11. Regarding claim 6, Leysieffer discloses at column 8, lines 52-57 that the signal processor (13) generates impedance measuring signals, which inherently would be "predetermined".

12. Regarding claims 7 and 25, as broadly as claimed, any test signal has a frequency that is within some (predetermined) range of a resonant frequency of an actuator. Additionally, Leysieffer discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies, which inherently requires the signal generator to output test signals at those resonant frequencies.

13. Regarding claim 8, Leysieffer discloses in Fig. 11 and describes at column 20, line 64 through column 21, line 13, a partially-implanted hearing aid in which the signal processor is disposed in an external unit, and in which the test signals are inherently transmitted transcutaneously between the external unit and the implanted actuator. Although Leysieffer does not explicitly state that the test signals are transmitted between an external transmitter and a subcutaneous coil, Leysieffer does explicitly disclose at column 13, line 66 through column 14, line 3 that the transcutaneous

communication of signals between the implanted unit 12 and external system 22 in the fully implanted hearing aid system of Fig. 1 is performed wirelessly by way of an inductive coupling coil. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to utilize the same transmission method in the embodiment of Fig. 11.

14. Regarding claim 9, Official notice is taken that it is notoriously well known in the art to include in an implanted hearing aid an implanted microphone for reception of the external acoustical signals which are to be processed by the hearing aid for presentation to the user of the hearing aid (as disclosed by Leysieffer in Fig. 10), and that further, it is well known to supply acoustic test signals to the implanted hearing aid through the implanted microphone in order to test the operation of the hearing aid. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to apply this well-known method to the system of Leysieffer and supply the test signals to the implanted actuator(16) of Fig. 10 through the implanted microphone (10).

15. Regarding claims 10, 11, 28, and 30, as described above regarding claims 2, 3, 21, and 22, Leysieffer discloses that means are provided for objectively determining the quality of coupling between the output transducer (actuator) and the coupled auditory element based on the measured impedance (magnetic field in the system of Leysieffer, modified according to the teachings of Durant). Additionally, Leysieffer discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies. Objective determination based on measured quantities inherently

comprises comparing the measured quantities (magnetic field measures in the system of Leysieffer, modified according to the teachings of Durant) to one or more predetermined ranges using appropriate means; and testing the quality of the actuator coupling to an auditory element as disclosed by Leysieffer will inherently indicate if the hearing aid is operational and thus will implicitly meet the limitation of claim 28 and perform the step claimed by claim 10.

16. Regarding claim 12, Leysieffer discloses at column 6, lines 54-62 that if the coupling quality of the output transducer (actuator) is judged inadequate, it can be improved. One of ordinary skill in the art would conclude that such improvement would be achieved by repositioning the actuator to achieve a desirable interface.

17. Regarding claims 16 and 29, the normal method of use of the remote current sensor of Durant according to Fig. 1a would include obtaining a first measurement of the magnetic field at a first location (the location of sensor A, element 20); obtaining a second measurement of the magnetic field at a second location (the location of sensor B, element 22); providing an output indicative of the first and second measurements of the magnetic field (the output including a measure of the current, "I" and the distance, "r" from sensor A (20) to the source of the magnetic field as described at column 4, lines 1-12). In the system of Leysieffer, modified to include the remote current sensor of Durant, it would have been obvious to one of ordinary skill in the art at the time the present invention was made to use the calculated distance output, "r" to determine a desired position of the test device that is as close as possible to the source of the

magnetic field in order to achieve maximum accuracy in the obtained current measurement.

18. Regarding claims 17 and 26, Leysieffer discloses at column 8, lines 1-17 that impedance measurements are made at frequencies extending over the entire transmission frequency range of the output transducer (actuator), which inherently requires providing a plurality of predetermined test signals having different frequencies distributed across a predetermined frequency range for use in generating a corresponding plurality of electrical signals passing through the actuator.

19. Regarding claims 18 and 27, in the system of Leysieffer, modified according to the teachings of Durand as described above, the system would be configured to measure a plurality of magnetic field measures corresponding to the plurality of electric signals passing through the actuator and the normal method of utilizing the test device would include using the test device to obtain a plurality of magnetic field measures corresponding to the plurality of electrical signals passing through the actuator.

20. Regarding claim 19, Leysieffer discloses at column 8, lines 23-31, means for detecting (and thus identifying) the spectral distribution of resonance frequencies of the transducer in the course of the impedance measured as a function of the frequency of the stimulation signal; and such means would presumably be used to perform the stated function.

21. Regarding claim 31, the system of Leysieffer comprises an oscillator (DSP 13) for generating the test signal; a test control processor (microcontroller 17) to set the

oscillator to generate the test signal; and a reference transmitter (element 75 of Fig. 11) to provide the test signal to the actuator.

22. Regarding claim 32, the remote current sensor system of Fig. 1a of Durant comprises a pair of sensors (20 and 22) for measuring the magnetic field of an implanted device. Durant discloses at column 3, lines 37-38 that the sensors may include, but are not limited to magneto-sensors such as the Phillips K210. Official notice is taken that it was notoriously well-known in the art at the time the present invention was made to utilize conductive coils to obtain a quantitative measure of a surrounding time-varying (AC) magnetic field. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to utilize a pair of coils as the magnetic field sensing elements in the system of Durant, incorporated into the external unit (76) of Fig. 11 of Leysieffer, as described above to obtain a measure of the current passing through the implanted actuator.

23. Regarding claim 33, Leysieffer discloses at column 18, lines 31-34 that the electromechanical output transducer generally may be designed as any electromagnetic, electrodynamic, piezoelectric, magnetostrictive, or dielectric transducer. An electrodynamic transducer would inherently include a vibratory member to stimulate a component of the auditory system.

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claims 1-7, 9-13, and 16-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of copending Application No. 10/083,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 20 of the copending application includes all the limitations of claim 1 in the instant application, and claims 2-7, 9-13, and 16-18 are obvious variations of claim 20 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

26. Claims 13-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims (and subject to overcoming the provisional double patenting rejections stated above).

27. The following is a statement of reasons for the indication of allowable subject matter: A method for assessing the coupling performance of an implanted-actuator hearing aid comprising measuring the magnetic field generated by the actuator in response to a signal passing through the actuator, in combination with an electrically-operated actuator positioning device is not taught or fairly suggested in the prior art.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

29. Leysieffer et al. (USPN 6,398,717) disclose a device for coupling of an electromechanical hearing aid transducer to an auditory element, such as an ossicle of the middle ear, referenced (as application Ser. No. 09/576,009) at column 19, lines 1-15 of Leysieffer (USPN 6,554,762), used in the rejections above.

30. Engebretson et al. (USPN 5,085,628) disclose an implantable hearing aid coupler device with the teaching of matching the mechanical output impedance of the actuator to the mechanical input impedance of the coupled auditory element.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony M. Jacobson whose telephone number is (703) 305-5532. The examiner can normally be reached on Mon. -Fri. 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Forester W. Isen can be reached on (703) 305-4386. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9314 for regular communications and (703) 872-9315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4750.

tmj
May 19, 2003

FORESTER W. ISEN
SUPERVISORY PATENT EXAMINER
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